

National Cancer Institute
Institutional Review Board
AGENDA (*revised 10/29/14)
November 3, 2014
1:00—5:30 pm
10 CRC/3-1608

- 1. Review of Draft Minutes, October 20, 2014**
- 2. Announcements**
- 3. Old Business**
- 4. New Business**
- 5. Problem Report Forms**
- 6. Other Expedited Actions**
- 7. Continuing Reviews**
- 8. Amendment** 13C0118-I, "A Phase I Trial of TRC102 (methoxyamine HCl) in Combination with Temozolomide in Patients with Relapsed Solid Tumors and Lymphomas" - Shivaani Kumar, PI
- 9. Amendment** 13C0083-A, "Efficacy of Adjuvant Mitotane Treatment in Prolonging Recurrence-free Survival in Patients with Adrenocortical Carcinoma at Low-intermediate Risk of Recurrence" - Tito Fojo, PI
- 10. Amendment** 14C0001-C, "Phase II Study of Axitinib (AG-013736) with Evaluation of the VEGF-pathway in Metastatic, Recurrent or Primary Unresectable Pheochromocytoma/Paraganglioma" - Tito Fojo, PI
- 11. Amendment** 11C0225-I, "First In-Human Phase I Trial of NHS-IL12 in Patients with Metastatic Solid Tumors" - James L Gulley, MD PhD, PI
- 12. Amendment** 10C0025-K, "Randomized Phase II Trial of Rituximab with Either Pentostatin or Bendamustine for Multiply Relapsed or Refractory Hairy Cell Leukemia" - Robert Kreitman, PI

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- 13. Amendment** 14C0059-C, "A Phase I Trial of T Cells Expressing an anti-GD2 Chimeric Antigen Receptor in Children and Young Adults with Non-neuroblastoma, GD2+ Solid Tumors" - Crystal Mackall, PI
- 14. Amendment** 11C0266-K, "A Phase I/II Study of the Safety and Feasibility of Administering T Cells Expressing Anti-EGFRvIII Chimeric Antigen Receptor to Patients with Malignant Gliomas Expressing EGFRvIII" - Steve Rosenberg, PI
- 15. Amendment** 12C0116-H, "A Phase II Study of Lymphodepletion followed by Autologous Tumor-Infiltrating Lymphocytes and High-Dose Aldesleukin for Human Papillomavirus-Associated Cancers" - Steve Rosenberg, PI
- 16. *Amendment** 12C0112-H, "Phase I Study of T Cells Expressing an Anti-CD19 Chimeric Receptor in Children and Young Adults with B Cell Malignancies"—Daniel Lee, PI
- 17. Initial Review** P141666, "Safety and Feasibility of Stem Cell Gene Transfer Following R-EPOCH for Non-Hodgkin Lymphoma in AIDS Patients Using Peripheral Blood Stem/Progenitor Cells Treated with a Lentivirus Vector-Encoding Multiple Anti-HIV RNAs" - Kieron Dunleavy, PI